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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,981	11/20/2001	Helen H. Hobbs	18781-007320	1693

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EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/989,981	HOBBS ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2.08.2002 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-70 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-70 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21 and 36-37, drawn to a method for making an ABCG8 polypeptide comprising an isolated nucleic acid molecule, expression cassettes, and cells comprising the same, classified in class 536, subclass 23.1, for example.

II. Claims 22-34, drawn to an isolated ABCG8 polypeptide, classified in class 514, subclass 2, for example.

III. Claim 35, drawn to an antibody, classified in class 530, subclass 387.1, for example.

IV. Claims 38-47, drawn to a method of identifying a compound useful in the treatment or prevention of a sterol-related disorder, said method comprising contacting an ABCG8 polypeptide with a test agent, classification dependent upon structure of agent.

V. Claims 48-60, drawn to a method of identifying a compound useful in the treatment or prevention of a sterol-related disorder, said method comprising contacting cell with a test agent, classification dependent upon structure of agent.

VI. Claims 61-68, drawn to a method of treating or preventing a sterol-related disorder in a mammal, classification dependent upon structure of agent.

VII. Claims 69 and 70, drawn to a method of prescreening to identify a candidate therapeutic agent that modulates ABCG8 activity in a mammal, classification dependent upon structure of agent.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, IV, V, VI, and VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of recombinant production and isolation of a polypeptide, which is not required by any of the other Inventions. Invention IV requires search and consideration of contacting an ABCG8 polypeptide with a test agent, which is not required by any of the other Inventions. Invention V requires search and consideration of contacting a cell with a test agent, which is not required by any of the other Inventions. Invention VI requires search and consideration of treating or preventing a sterol-related disorder in a mammal, which is not required by any of the other Inventions. Invention VII requires search and consideration of an agent that modulates ABCG8 activity in a mammal, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions II and III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Although the polypeptide of Invention II can be used to obtain the antibody of Invention III, it

can be made using materially different methods, such isolation from natural sources or chemical synthesis. Although the antibody of Invention III can be used to obtain the polypeptide of Invention II it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods.

5. Inventions II and each of IV, V, VI, and VII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The polypeptide of Invention II can be used to isolate receptors.

6. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. The isolated polypeptide of Invention II can be isolated from natural sources or chemically synthesized.

7. Inventions III and each of I, IV, V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each of I, IV, V, VI, and VII are unrelated product and methods, wherein each is not required, one for another. For example, the

claimed methods of Inventions I, IV, V, VI, and VII do not recite the use or production of the antibody of Invention III.

8. FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims 1-70, each in part, as the inventions pertain to SEQ ID NO: 1.

B. Claims 1-70, each in part, as the inventions pertain to SEQ ID NO: 2.

C. Claims 1-70, each in part, as the inventions pertain to SEQ ID NO: 3.

D. Claims 1-70, each in part, as the inventions pertain to SEQ ID NO: 4.

E. Claims 1-70, each in part, as the inventions pertain to SEQ ID NO: 5.

F. Claims 1-70, each in part, as the inventions pertain to SEQ ID NO: 6.

G. Claims 1-70, each in part, as the inventions pertain to SEQ ID NO: 7.

H. Claims 1-70, each in part, as the inventions pertain to SEQ ID NO: 8.

9. The inventions are distinct, each from the other because of the following reasons:

10. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Inventions A, B, C, D, E, F, G, and H are directed to sequences that are distinct both physically and functionally, and are not required one for the other. Invention A requires search and consideration of SEQ ID NO: 1, which is not required by any of the other Inventions. Invention B requires search and consideration of SEQ ID NO: 2, which is not

required by any of the other Inventions. Invention C requires search and consideration of SEQ ID NO: 3, which is not required by any of the other Inventions. Invention D requires search and consideration of SEQ ID NO: 4, which is not required by any of the other Inventions. Invention E requires search and consideration of SEQ ID NO: 5, which is not required by any of the other Inventions. Invention F requires search and consideration of SEQ ID NO: 6, which is not required by any of the other Inventions. Invention G requires search and consideration of SEQ ID NO: 7, which is not required by any of the other Inventions. Invention H requires search and consideration of SEQ ID NO: 8, which is not required by any of the other Inventions. Each sequence requires a separate search of the literature and sequence databases. A search and examination of an Invention as it pertains to all sequences would therefore present the examiner with an undue search burden.

11. Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect one group from I-VII. In order to be fully responsive, Applicant must elect one group from I-VII and one group from A-H.

12. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Hypercholesterolemia

b. Hyperlipidemia

c. Gall stones

d. HDL deficiency

e. Atheroscelrosis

f. Nutritional deficiencies

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 47 and 64 are generic.

14. If applicant selects Invention IV or VI, one species from the sterol-related disorder group must be chosen to be fully responsive.

15. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

16. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols, Ph.D. whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth C. Kemmerer

CJN
November 18th, 2002

ELIZABETH C. KEMMERER
PRIMARY EXAMINER